

1. INTRODUCTION

1.1 WATER QUALITY CRITERIA AND STANDARDS

Pursuant to Section 304(a)(1) of the Clean Water Act (CWA), the U.S. Environmental Protection Agency (EPA) is required to publish, and from time to time thereafter revise, criteria for water quality accurately reflecting the latest scientific knowledge on the kind and extent of all identifiable effects on human health which may be expected from the presence of pollutants in any body of water.

Historically, the ambient water quality criteria (AWQC or 304(a) criteria) provided two essential types of information: (1) discussions of available scientific data on the effects of the pollutants on public health and welfare, aquatic life, and recreation; and (2) quantitative concentrations or qualitative assessments of the levels of pollutants in water which, if not exceeded, will generally ensure adequate water quality for a specified water use. Water quality criteria developed under Section 304(a) are based solely on data and scientific judgments on the relationship between pollutant concentrations and environmental and human health effects. The 304(a) criteria do not reflect consideration of economic impacts or the technological feasibility of meeting the criteria in ambient water. These 304(a) criteria may be used as guidance by States and authorized Tribes to establish water quality standards, which ultimately provide a basis for controlling discharges or releases of pollutants into ambient waters.

In 1980, AWQC were derived for 64 pollutants using guidelines developed by the Agency for calculating the impact of waterborne pollutants on aquatic organisms and on human health. Those guidelines consisted of systematic procedures for assessing valid and appropriate data concerning a pollutant's acute and chronic adverse effects on aquatic organisms, nonhuman mammals, and humans.

1.2 PURPOSE OF THIS DOCUMENT

The *Methodology for Deriving Ambient Water Quality Criteria for the Protection of Human Health (2000)* (hereafter the "2000 Human Health Methodology") addresses the development of AWQC to protect human health. The Agency intends to use the 2000 Human Health Methodology both to develop new AWQC for additional pollutants and to revise existing AWQC. Within the next several years, EPA intends to focus on deriving AWQC for chemicals of high priority (including, but not limited to, mercury, arsenic, PCBs, and dioxin). Furthermore, EPA anticipates that 304(a) criteria development in the future will be for bioaccumulative chemicals and pollutants considered highest priority by the Agency. The 2000 Human Health Methodology is also intended to provide States and authorized Tribes flexibility in establishing water quality standards by providing scientifically valid options for developing their own water quality criteria that consider local conditions. States and authorized Tribes are strongly encouraged to use this Methodology to derive their own AWQC. However, the 2000 Human Health Methodology also defines the default factors EPA intends to use in evaluating and determining consistency of State water quality standards with the requirements of the CWA. The

Agency intends to use these default factors to calculate national water quality criteria under Section 304(a) of the Act. EPA will also use this Methodology as guidance when promulgating water quality standards for a State or Tribe under Section 303(c) of the CWA.

This Methodology does not substitute for the CWA or EPA's regulations; nor is it a regulation itself. Thus, the 2000 Human Health Methodology cannot impose legally-binding requirements on EPA, States, Tribes or the regulated community, and may not apply to a particular situation based upon the circumstances. EPA and State/Tribal decision-makers retain the discretion to use different, scientifically defensible, methodologies to develop human health criteria on a case-by-case basis that differ from this Methodology where appropriate. EPA may change the Methodology in the future through intermittent refinements as advances in science or changes in Agency policy occur.

The 2000 Human Health Methodology incorporates scientific advancements made over the past two decades. The use of this Methodology is an important component of the Agency's efforts to improve the quality of the Nation's waters. EPA believes the Methodology will enhance the overall scientific basis of water quality criteria. Further, the Methodology should help States and Tribes address their unique water quality issues and risk management decisions, and afford them greater flexibility in developing their water quality programs.

There are three companion Technical Support Document (TSD) volumes for the 2000 Human Health Methodology: a Risk Assessment TSD; an Exposure Assessment TSD; and a Bioaccumulation TSD. These documents are intended to further support States and Tribes in developing AWQC to reflect local conditions. The Risk Assessment TSD (USEPA, 2000) is being published concurrently with this Methodology. Publication of the Exposure Assessment and Bioaccumulation TSDs are anticipated in 2001.

1.3 HISTORY OF THE AMBIENT WATER QUALITY CRITERIA (AWQC) METHODOLOGY

In 1980, EPA published AWQC for 64 pollutants/pollutant classes identified in Section 307(a) of the CWA and provided a methodology for deriving the criteria (USEPA, 1980). These 1980 AWQC National Guidelines (or the "1980 Methodology") for developing AWQC for the protection of human health addressed three types of endpoints: noncancer, cancer, and organoleptic (taste and odor) effects. Criteria for protection against noncancer and cancer effects were estimated by using risk assessment-based procedures, including extrapolation from animal toxicity or human epidemiological studies. Basic human exposure assumptions were applied to the criterion equation.

The risk assessment-based procedures used to derive the AWQC to protect human health were specific to whether the endpoint was cancer or noncancer. When using cancer as the critical risk assessment endpoint (which had been assumed not to have a threshold), the AWQC were

presented as a range of concentrations associated with specified incremental lifetime risk levels¹. When using noncancer effects as the critical endpoint, the AWQC reflected an assessment of a “no-effect” level, since noncancer effects were assumed to have a threshold. The key features of each procedure are described briefly in the following paragraphs.

Cancer effects. If human or animal studies on a contaminant indicated that it induced a statistically significant carcinogenic response, the 1980 AWQC National Guidelines treated the contaminant as a carcinogen and derived a low-dose cancer potency factor from available animal data using the linearized multistage model (LMS). The LMS, which uses a linear, nonthreshold assumption for low-dose risk, was used by the Agency as a science policy choice in protecting public health, and represented a plausible upper limit for low-dose risk. The cancer potency factor, which expresses incremental, lifetime risk as a function of the rate of intake of the contaminant, was then combined with exposure assumptions to express that risk in terms of an ambient water concentration. In the 1980 AWQC National Guidelines, the Agency presented a range of contaminant concentrations corresponding to incremental cancer risks of 10^{-7} to 10^{-5} (that is, a risk of one additional case of cancer in a population of ten million to one additional cancer case in a population of one hundred thousand, respectively).

Noncancer effects. If the pollutant was not considered to have the potential for causing cancer in humans (later defined as a known, probable, or possible human carcinogen by the 1986 *Guidelines for Carcinogen Risk Assessment*, USEPA, 1986d), the 1980 AWQC National Guidelines treated the contaminant as a noncarcinogen; a criterion was derived using a threshold concentration for noncancer adverse effects. The criteria derived from noncancer data were based on the Acceptable Daily Intake (ADI) (now termed the reference dose [RfD]). ADI values were generally derived using a no-observed-adverse-effect level (NOAEL) from animal studies, although human data were used whenever available. The ADI was calculated by dividing the NOAEL by an uncertainty factor to account for uncertainties inherent in extrapolating limited toxicological data to humans. In accordance with the National Research Council recommendations of 1977 (NRC, 1977), safety factors (SFs) (later redefined as uncertainty factors) of 10, 100, or 1,000 were used, depending on the quality of the data.

Organoleptic effects. Organoleptic characteristics were also used in developing criteria for some contaminants to control undesirable taste and/or odor imparted by them to ambient water. In some cases, a water quality criterion based on organoleptic effects would be more stringent than a criterion based on toxicologic endpoints. The 1980 AWQC National Guidelines emphasized that criteria derived for organoleptic endpoints are not based on toxicological information, have no direct relationship to adverse human health effects and, therefore, do not necessarily represent approximations of acceptable risk levels for humans.

¹Throughout this document, the term “risk level” regarding a cancer assessment using linear approach refers to an upper-bound estimate of excess lifetime cancer risk.

1.4 RELATIONSHIP OF WATER QUALITY STANDARDS TO AWQC

Under Section 303(c) of the CWA, States have the primary responsibility for establishing water quality standards, defined under the Act as designated beneficial uses of a water segment and the water quality criteria necessary to support those uses. Additionally, Native American Tribes authorized to administer the water quality standards program under 40 CFR 131.8 establish water quality standards for waters within their jurisdictions. This statutory framework allows States and authorized Tribes to work with local communities to adopt appropriate designated uses and to adopt criteria to protect those designated uses. Section 303(c) provides for EPA review of water quality standards and for promulgation of a superseding Federal rule in cases where State or Tribal standards are not consistent with the applicable requirements of the CWA and the implementing Federal regulations, or where the Agency determines Federal standards are necessary to meet the requirements of the Act. Section 303(c)(2)(B) specifically requires States and authorized Tribes to adopt water quality criteria for toxics for which EPA has published criteria under Section 304(a) and for which the discharge or presence could reasonably be expected to interfere with the designated use adopted by the State or Tribe. In adopting such criteria, States and authorized Tribes must establish numerical values based on one of the following: (1) 304(a) criteria; (2) 304(a) criteria modified to reflect site-specific conditions; or, (3) other scientifically defensible methods. In addition, States and authorized Tribes can establish narrative criteria where numeric criteria cannot be determined.

It must be recognized that the Act uses the term “criteria” in two different ways. In Section 303(c), the term is part of the definition of a water quality standard. Specifically, a water quality standard is composed of designated uses and the criteria necessary to protect those uses. Thus, States and authorized Tribes are required to adopt regulations which contain legally enforceable criteria. However, in Section 304(a) the term criteria is used to describe the scientific information that EPA develops to be used as guidance by States, authorized Tribes and EPA when establishing water quality standards pursuant to 303(c). Thus, two distinct purposes are served by the 304(a) criteria. The first is as guidance to the States and authorized Tribes in the development and adoption of water quality criteria which will protect designated uses, and the second is as the basis for promulgation of a superseding Federal rule when such action is necessary.

1.5 NEED FOR THE AWQC METHODOLOGY REVISIONS

Since 1980, EPA risk assessment practices have evolved significantly in all of the major Methodology areas: that is, cancer and noncancer risk assessments, exposure assessments, and bioaccumulation. When the 1980 Methodology was developed, EPA had not yet developed formal cancer or noncancer risk assessment guidelines. Since then, EPA has published several risk assessment guidelines. In cancer risk assessment, there have been advances in the use of mode of action (MOA) information to support both the identification of potential human carcinogens and the selection of procedures to characterize risk at low, environmentally relevant exposure levels. EPA published *Proposed Guidelines for Carcinogen Risk Assessment* (USEPA, 1996a, hereafter the “1996 proposed cancer guidelines”). These guidelines presented revised

procedures to quantify cancer risk at low doses, replacing the current default use of the LMS model. Following review by the Agency's Science Advisory Board (SAB), EPA published the revised *Guidelines for Carcinogen Risk Assessment—Review Draft* in July 1999 (USEPA, 1999a, hereafter the “1999 draft revised cancer guidelines”). In noncancer risk assessment, the Agency is moving toward the use of the benchmark dose (BMD) and other dose-response approaches in place of the traditional NOAEL approach to estimate an RfD or Reference Concentration (RfC). *Guidelines for Mutagenicity Risk Assessment* were published in 1986 (USEPA, 1986b). In 1991, the Agency published *Guidelines for Developmental Toxicity Risk Assessment* (USEPA, 1991), and it issued *Guidelines for Reproductive Toxicity Risk Assessment* in 1996 (USEPA, 1996b). In 1998, EPA published final *Guidelines for Neurotoxicity Risk Assessment* (USEPA, 1998), and in 1999 it issued the draft *Guidance for Conducting Health Risk Assessment of Chemical Mixtures* (USEPA, 1999b).

In 1986, the Agency made available to the public the Integrated Risk Information System (IRIS). IRIS is a database that contains risk information on the cancer and noncancer effects of chemicals. The IRIS assessments are peer reviewed and represent EPA consensus positions across the Agency's program and regional offices.

New studies have addressed water consumption and fish tissue consumption. These studies provide a more current and comprehensive description of national, regional, and special-population consumption patterns that EPA has reflected in the 2000 Human Health Methodology. In addition, more formalized procedures are now available to account for human exposure from multiple sources when setting health goals such as AWQC that address only one exposure source. In 1986, the Agency published the *Total Exposure Assessment Methodology (TEAM) Study: Summary and Analysis, Volume I, Final Report* (USEPA, 1986c), which presents a process for conducting comprehensive evaluation of human exposures. In 1992, EPA published the revised *Guidelines for Exposure Assessment* (USEPA, 1992), which describe general concepts of exposure assessment, including definitions and associated units, and provide guidance on planning and conducting an exposure assessment. The *Exposure Factors Handbook* was updated in 1997 (USEPA, 1997a). Also in 1997, EPA developed *Guiding Principles for Monte Carlo Analysis* (USEPA, 1997b) and published its *Policy for Use of Probabilistic Analysis in Risk Assessment* (see <http://www.epa.gov/ncea/mcpolicy.htm>). The Monte Carlo guidance can be applied to exposure assessments and risk assessments. The Agency has recently developed the Relative Source Contribution (RSC) Policy for assessing total human exposure to a contaminant and apportioning the RfD among the media of concern, published for the first time in this Methodology.

The Agency has moved toward the use of a bioaccumulation factor (BAF) to reflect the uptake of a contaminant from all sources (e.g., ingestion, sediment) by fish and shellfish, rather than just from the water column as reflected by the use of a bioconcentration factor (BCF) in the 1980 Methodology. The Agency has also developed detailed procedures and guidelines for estimating BAF values.

Another reason for the 2000 Human Health Methodology is the need to bridge the gap between the differences in the risk assessment and risk management approaches used by EPA's Office of Water for the derivation of AWQC under the authority of the CWA and Maximum Contaminant Level Goals (MCLGs) under the Safe Drinking Water Act (SDWA). Three notable differences are the treatment of chemicals designated as Group C, possible human carcinogens under the 1996 proposed cancer guidelines, the consideration of non-water sources of exposure when setting an AWQC or MCLG for a noncarcinogen, and cancer risk ranges. Those three differences are described in the three subsections below, respectively.

1.5.1 Group C Chemicals

Chemicals were typically classified as Group C—i.e., possible human carcinogens—under the existing (1986) EPA cancer classification scheme for any of the following reasons:

- 1) Carcinogenicity has been documented in only one test species and/or only one cancer bioassay and the results do not meet the requirements of “sufficient evidence.”
- 2) Tumor response is of marginal statistical significance due to inadequate design or reporting.
- 3) Benign, but not malignant, tumors occur with an agent showing no response in a variety of short-term tests for mutagenicity.
- 4) There are responses of marginal statistical significance in a tissue known to have a high or variable background rate.

The 1986 *Guidelines for Carcinogen Risk Assessment* (hereafter the “1986 cancer guidelines”) specifically recognized the need for flexibility with respect to quantifying the risk of Group C, possible human carcinogens. The 1986 cancer guidelines noted that agents judged to be in Group C, possible human carcinogens, may generally be regarded as suitable for quantitative risk assessment, but that case-by-case judgments may be made in this regard.

The EPA Office of Water has historically treated Group C chemicals differently under the CWA and the SDWA. It is important to note that the 1980 AWQC National Guidelines for setting AWQC under the CWA predated EPA's carcinogen classification system, which was proposed in 1984 (USEPA, 1984) and finalized in 1986 (USEPA, 1986a). The 1980 AWQC National Guidelines did not explicitly differentiate among agents with respect to the weight of evidence for characterizing them as likely to be carcinogenic to humans. For all pollutants judged as having adequate data for quantifying carcinogenic risk—including those now classified as Group C—AWQC were derived based on data on cancer incidence. In the 1980 AWQC National Guidelines, EPA emphasized that the AWQC for carcinogens should state that the recommended concentration for maximum protection of human health is zero. At the same time, the criteria

published for specific carcinogens presented water concentrations for these pollutants corresponding to individual lifetime excess cancer risk levels in the range of 10^{-7} to 10^{-5} .

In the development of national primary drinking water regulations under the SDWA, EPA is required to promulgate a health-based MCLG for each contaminant. The Agency policy has been to set the MCLG at zero for chemicals with strong evidence of carcinogenicity associated with exposure from water. For chemicals with limited evidence of carcinogenicity, including many Group C agents, the MCLG was usually obtained using an RfD based on the pollutant's noncancer effects with the application of an additional uncertainty factor of 1 to 10 to account for carcinogenic potential of the chemical. If valid noncancer data for a Group C agent were not available to establish an RfD but adequate data are available to quantify the cancer risk, then the MCLG was based upon a nominal lifetime excess cancer risk in the range of 10^{-6} to 10^{-5} (ranging from one case in a population of one million to one case in a population of one hundred thousand). Even in those cases where the RfD approach has been used for the derivation of the MCLG for a Group C agent, the drinking water concentrations associated with excess cancer risks in the range of 10^{-6} to 10^{-5} were also provided for comparison.

It should also be noted that EPA's pesticides program has applied both of the previously described methods for addressing Group C chemicals in actions taken under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and finds both methods applicable on a case-by-case basis. Unlike the drinking water program, however, the pesticides program does not add an extra uncertainty factor to account for potential carcinogenicity when using the RfD approach.

In the 1999 draft revised cancer guidelines, there are no more alphanumeric categories. Instead, there will be longer narratives for hazard characterization that will use consistent descriptive terms when assessing cancer risk.

1.5.2 Consideration of Non-water Sources of Exposure

The 1980 AWQC National Guidelines recommended that contributions from non-water sources, namely air and non-fish dietary intake, be subtracted from the Acceptable Daily Intake (ADI), thus reducing the amount of the ADI "available" for water-related sources of intake. In practice, however, when calculating human health criteria, these other exposures were generally not considered because reliable data on these exposure pathways were not available. Consequently, the AWQC were usually derived such that drinking water and fish ingestion accounted for the entire ADI (now called RfD).

In the drinking water program, a similar "subtraction" method was used in the derivation of MCLGs proposed and promulgated in drinking water regulations through the mid-1980s. More recently, the drinking water program has used a "percentage" method in the derivation of MCLGs for noncarcinogens. In this approach, the percentage of total exposure typically accounted for by drinking water, referred to as the relative source contribution (RSC), is applied to the RfD to determine the maximum amount of the RfD "apportioned" to drinking water reflected by the MCLG value. In using this percentage procedure, the drinking water program

also applies a ceiling level of 80 percent of the RfD and a floor level of 20 percent of the RfD. That is, the MCLG cannot account for more than 80 percent of the RfD, nor less than 20 percent of the RfD.

The drinking water program usually takes a conservative approach to public health by applying an RSC factor of 20 percent to the RfD when adequate exposure data do not exist, assuming that the major portion (80 percent) of the total exposure comes from other sources, such as diet.

In the 2000 Human Health Methodology, guidance for the routine consideration of non-water sources of exposure [both ingestion exposures (e.g., food) and exposures other than the oral route (e.g., inhalation)] is presented. The approach is called the Exposure Decision Tree. Relative source contribution estimates will be made by EPA using this approach, which allows for use of either the subtraction or percentage methods, depending on chemical-specific circumstances, within the 20 to 80 percent range described above.

1.5.3 Cancer Risk Ranges

In addition to the different risk assessment approaches discussed above for deriving AWQC and MCLGs for Group C agents, there have been different risk management approaches by the drinking water and surface water programs on lifetime excess risk values when setting health-based criteria for carcinogens. The surface water program has derived AWQC for carcinogens that generally corresponded to lifetime excess cancer risk levels of 10^{-7} to 10^{-5} . The drinking water program has set MCLGs for Group C agents based on a slightly less stringent risk range of 10^{-6} to 10^{-5} , while MCLGs for chemicals with strong evidence of carcinogenicity (that is, classified as Group A, known, or B probable, human carcinogen) are set at zero. The drinking water program is now following the principles of the 1999 draft revised cancer guidelines to determine the type of low-dose extrapolation based on mode of action.

It is also important to note that under the drinking water program, for those substances having an MCLG of zero, enforceable Maximum Contaminant Levels (MCLs) have generally been promulgated to correspond with cancer risk levels ranging from 10^{-6} to 10^{-4} . Unlike AWQC and MCLGs which are strictly health-based criteria, MCLs are developed with consideration given to the costs and technological feasibility of reducing contaminant levels in water to meet those standards.

With the 2000 Human Health Methodology, EPA will publish its national 304(a) water quality criteria at a 10^{-6} risk level, which EPA considers appropriate for the general population. EPA is increasing the degree of consistency between the drinking water and ambient water programs, given the somewhat different requirements of the CWA and SDWA.

1.6 OVERVIEW OF THE AWQC METHODOLOGY REVISIONS

The following equations for deriving AWQC include toxicological and exposure assessment parameters which are derived from scientific analysis, science policy, and risk management decisions. For example, values for parameters such as a field-measured BAF or a point of departure from an animal study [in the form of a lowest-observed-adverse-effect level (LOAEL)/no-observed -adverse-effect level (NOAEL)/lower 95 percent confidence limit on a dose associated with a 10 percent extra risk (LED₁₀)] are empirically measured using scientific methods. By contrast, the decision to use animal effects as surrogates for human effects involves judgment on the part of the EPA (and similarly, by other agencies) as to the best practice to follow when human data are lacking. Such a decision is, therefore, a matter of science policy. The choice of default fish consumption rates for protection of a certain percentage (i.e., the 90th percentile) of the general population is clearly a risk management decision. In many cases, the Agency has selected parameter values using its best judgment regarding the overall protection afforded by the resulting AWQC when all parameters are combined. For a longer discussion of the differences between science, science policy, and risk management, please refer to Section 2 of this document. Section 2 also provides further details with regard to risk characterization for this Methodology, with emphasis placed on explaining the uncertainties in the overall risk assessment.

The generalized equations for deriving AWQC based on noncancer effects are:

Noncancer Effects²

$$AWQC = RfD \cdot RSC \cdot \left(\frac{BW}{DI + \sum_{i=2}^4 (FI_i \cdot BAF_i)} \right) \quad (\text{Equation 1-1})$$

Cancer Effects: Nonlinear Low-Dose Extrapolation

$$AWQC = \frac{POD}{UF} \cdot RSC \cdot \left(\frac{BW}{DI + \sum_{i=2}^4 (FI_i \cdot BAF_i)} \right) \quad (\text{Equation 1-2})$$

² Although appearing in this equation as a factor to be multiplied, the RSC can also be an amount subtracted. Refer to the explanation key below the equations.

Cancer Effects: Linear Low-Dose Extrapolation

$$AWQC = RSD \cdot \left(\frac{BW}{DI + \sum_{i=2}^4 (FI_i \cdot BAF_i)} \right) \quad (\text{Equation 1-3})$$

where:

AWQC	=	Ambient Water Quality Criterion (mg/L)
RfD	=	Reference dose for noncancer effects (mg/kg-day)
POD	=	Point of departure for carcinogens based on a nonlinear low-dose extrapolation (mg/kg-day), usually a LOAEL, NOAEL, or LED ₁₀
UF	=	Uncertainty Factor for carcinogens based on a nonlinear low-dose extrapolation (unitless)
RSD	=	Risk-specific dose for carcinogens based on a linear low-dose extrapolation (mg/kg-day) (dose associated with a target risk, such as 10 ⁻⁶)
RSC	=	Relative source contribution factor to account for non-water sources of exposure. (Not used for linear carcinogens.) May be either a percentage (multiplied) or amount subtracted, depending on whether multiple criteria are relevant to the chemical.
BW	=	Human body weight (default = 70 kg for adults)
DI	=	Drinking water intake (default = 2 L/day for adults)
FI _i	=	Fish intake at trophic level (TL) I (I = 2, 3, and 4) (defaults for total intake = 0.0175 kg/day for general adult population and sport anglers, and 0.1424 kg/day for subsistence fishers). Trophic level breakouts for the general adult population and sport anglers are: TL2 = 0.0038 kg/day; TL3 = 0.0080 kg/day; and TL4 = 0.0057 kg/day.
BAF _i	=	Bioaccumulation factor at trophic level I (I=2, 3 and 4), lipid normalized (L/kg)

For highly bioaccumulative chemicals where ingestion from water might be considered negligible, EPA is currently evaluating the feasibility of developing and implementing AWQCs that are expressed in terms of concentrations in tissues of aquatic organisms. Such tissue residue criteria might be used as an alternative to AWQCs which are expressed as concentrations in water, particularly in situations where AWQCs are at or below the practical limits for quantifying a chemical in water. Even though tissue residue criteria would not require the use of a BAF in their derivation, implementing such criteria would still require a mechanism for relating chemical loads and concentrations in water and sediment to concentrations in tissues of appropriate fish and shellfish (e.g., a BAF or bioaccumulation model). At this time, no revisions are planned to the Methodology to provide specific guidance on developing fish tissue-based water quality criteria.

However, guidance may be provided in the future either as a separate document or integrated in a specific 304(a) water quality criteria document for a chemical that warrants such an approach.

AWQC for the protection of human health are designed to minimize the risk of adverse effects occurring to humans from chronic (lifetime) exposure to substances through the ingestion of drinking water and consumption of fish obtained from surface waters. The Agency is not recommending the development of additional water quality criteria similar to the “drinking water health advisories” that focus on acute or short-term effects; these are not seen as routinely having a meaningful role in the water quality criteria and standards program. However, as discussed below, there may be some instances where the consideration of acute or short-term toxicity and exposure in the derivation of AWQC is warranted.

Although the AWQC are based on chronic health effects data (both cancer and noncancer effects), the criteria are intended to also be protective against adverse effects that may reasonably be expected to occur as a result of elevated acute or short-term exposures. That is, through the use of conservative assumptions with respect to both toxicity and exposure parameters, the resulting AWQC should provide adequate protection not only for the general population over a lifetime of exposure, but also for special subpopulations who, because of high water- or fish-intake rates, or because of biological sensitivities, have an increased risk of receiving a dose that would elicit adverse effects. The Agency recognizes that there may be some cases where the AWQC based on chronic toxicity may not provide adequate protection for a subpopulation at special risk from shorter-term exposures. The Agency encourages States, Tribes, and others employing the 2000 Human Health Methodology to give consideration to such circumstances in deriving criteria to ensure that adequate protection is afforded to all identifiable subpopulations. (See Section 4.3, Factors Used in the AWQC Computation, for additional discussion of these subpopulations.)

The EPA is in the process of revising its cancer guidelines, including its descriptions of human carcinogenic potential. Once final guidelines are published, they will be the basis for assessment under this methodology. In the meanwhile, the 1986 guidelines are used and extended with principles discussed in EPA’s 1999 *Guidelines for Carcinogen Risk Assessment - Review Draft* (hereafter “1999 draft revised cancer guidelines”). These principles arise from new science about cancer discovered in the last 15 years and from EPA policy of recent years supporting full characterization of hazard and risk both for the general population and potentially sensitive groups such as children. These principles are incorporated in recent and ongoing assessments such as the reassessment of dioxin, consistent with the 1986 guidelines. Until final guidelines are published, information is presented to describe risk under both the old guidelines and draft revisions. Dose-response assessment under the 1986 guidelines employs a linearized multistage model to extrapolate tumor dose-response observed in animal or human studies down to zero dose, zero extra risk. The dose-response assessment under EPA’s 1999 draft revised cancer guidelines is a two-step process. In the first step, the response data are modeled in the range of empirical observation. Modeling in the observed range is done with biologically based or appropriate curve-fitting modeling. In the second step, extrapolation below the range of observation is accomplished by biologically based modeling if there are sufficient data or by a

default procedure (linear, nonlinear, or both). A point of departure (POD) for extrapolation is estimated from modeling observed data. The lower 95 percent confidence limit on a dose associated with 10 percent extra risk (LED_{10}) is the standard POD for low-dose extrapolation. The linear default procedure is a straight line extrapolation to the origin (i.e., zero dose, zero extra risk) from the POD, which is the LED_{10} identified in the observable response range. The result of this procedure is generally comparable (within 2-fold) to that of using a linearized multistage model under existing, 1986 guidelines. The linear low-dose extrapolation applies to agents that are best characterized by the assumption of linearity (e.g., direct DNA reactive mutagens) for their MOA. A linear approach would also be applied when inadequate or no information is available to explain the carcinogenic MOA; this is a science policy choice in the interest of public health. If it is determined that the MOA understanding fully supports a nonlinear extrapolation, the AWQC is derived using the nonlinear default which is based on a margin of exposure (MOE) analysis using the LED_{10} as the POD and applying uncertainty factors (UFs) to arrive at an acceptable MOE. There may be situations where it is appropriate to apply both the linear and nonlinear default procedures (e.g., for an agent that is both DNA reactive and active as a promoter at higher doses).

For substances that are carcinogenic, particularly those for which the MOA suggests nonlinearity at low doses, the Agency recommends that an integrated approach be taken in looking at cancer and noncancer effects. If one effect does not predominate, AWQC values should be determined for both carcinogenic and noncarcinogenic endpoints. The lower of the resulting values should be used for the AWQC.

When deriving AWQC for noncarcinogens and carcinogens based on a nonlinear low-dose extrapolation, a factor is included to account for other non-water exposure sources [both ingestion exposures (e.g., food) and exposures other than the oral route (e.g., inhalation)] so that the entire RfD, or POD/UF, is not apportioned to drinking water and fish consumption alone. Guidance is provided in the 2000 Human Health Methodology for determining the factor (i.e., the RSC) to be used for a particular chemical. The Agency is recommending the use of an Exposure Decision Tree procedure to support the determination of the appropriate RSC value for a given water contaminant. In the absence of data, the Agency intends to use 20 percent of the RfD (or POD/UF) as the default RSC in calculating 304(a) criteria or promulgating State or Tribal water quality standards under Section 303(c).

With AWQC derived for carcinogens based on a linear low-dose extrapolation, the Agency will publish recommended criteria values at a 10^{-6} risk level. States and authorized Tribes can always choose a more stringent risk level, such as 10^{-7} . EPA also believes that criteria based on a 10^{-5} risk level are acceptable for the general population as long as States and authorized Tribes ensure that the risk to more highly exposed subgroups (sportfishers or subsistence fishers) does not exceed the 10^{-4} level. Clarification on this risk management decision is provided in Section 2 of this document.

The default fish consumption value for the general adult population in the 2000 Human Health Methodology is 17.5 grams/day, which represents an estimate of the 90th percentile

consumption rate for the U.S. adult population based on the U.S. Department of Agriculture's (USDA's) Continuing Survey of Food Intake by Individuals (CSFII) 1994-96 data (USDA, 1998). EPA will use this default intake rate with future national 304(a) criteria derivations or revisions. This default value is chosen to be protective of the majority of the general population. However, States and authorized Tribes are urged to use a fish intake level derived from local data on fish consumption in place of this default value when deriving AWQC, ensuring that the fish intake level chosen is protective of highly exposed individuals in the population. EPA has provided default values for States and authorized Tribes that do not have adequate information on local or regional consumption patterns, based on numerous studies that EPA has reviewed on sport anglers and subsistence fishers. EPA's defaults for these population groups are estimates of their average consumption. EPA recommends a default of 17.5 grams/day for sport anglers as an approximation of their average consumption and 142.4 grams/day for subsistence fishers, which falls within the range of averages for this group. Consumption rates for women of childbearing age and children younger than 14 are also provided to maximize protection in those cases where these subpopulations may be at greatest risk.

In the 2000 Human Health Methodology, criteria are derived using a BAF rather than a BCF. To derive the BAF, States and authorized Tribes may use EPA's Methodology or any method consistent with this Methodology. EPA's highest preference in developing BAFs are BAFs based on field-measured data from local/regional fish.

1.7 REFERENCES

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